Remarks

Claims 1, 3, 4-9, 11 and 14 are pending in this application. By this Amendment, claims 7, 8 and 14 are amended, and claim 13 is canceled without prejudice to or disclaimer of the subject matter set forth therein. Support for the amendments to can be found in the specification as originally filed. No new matter is added by these amendments.

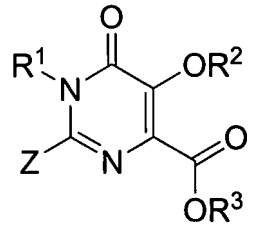
I. Claim Rejection Under 35 U.S.C. §112

The Office Action rejects claims 13 and 14 under 35 U.S.C. §112, first paragraph, because the specification allegedly does not provide enablement for a method of inhibiting hepatitis C virus generally and for a method of preventing an illness due to hepatitis C virus. While Applicants do not necessarily agree with this rejection, claim 13 is canceled, and claim 14 is amended herein. Reconsideration and withdrawal of the rejection are respectfully requested in light of these amendments.

II. Claim Rejection Under 35 U.S.C. §103

The Office Action rejects claims 1, 3-9, 11, 13 and 14 under 35 U.S.C. §103(a) over International Patent Publication WO 02/006246 to Gardelli et al. Applicants respectfully traverse this rejection with respect to claims 1, 3-9, 11 and 14, claim 13 having been canceled herein.

Independent claim 1, from which claims 3-9, 11 and 14 depend, sets forth, in pertinent part, a "compound of formula (I) below, or a pharmaceutically acceptable salt thereof:

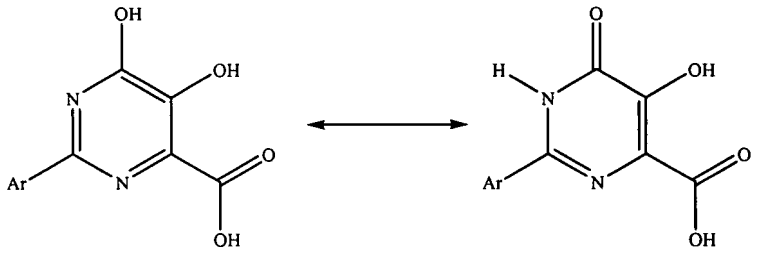


(I)

wherein Z represents C_{2-6} alkynyl, aryl or heteroaryl, any of which groups may be optionally substituted; R^1 represents C_{1-6} alkyl or aryl(C_{1-6})alkyl, either of which groups may be optionally substituted; R^2 represents hydrogen; or C_{1-6} alkyl, C_{2-6} alkylcarbonyl, aryl, arylcarbonyl, heteroaryl, aryl(C_{1-6})alkyl or heteroaryl(C_{1-6})alkyl, any of which

groups may be optionally substituted; and R^3 represents hydrogen, C_{1-6} alkyl, C_{3-7} heterocycloalkyl(C_{1-6})alkyl, di(C_{1-6})alkylamino(C_{1-6})alkyl, C_{2-6} alkylcarbonyloxy(C_{1-6})alkyl or C_{3-7} cycloalkoxycarbonyloxy(C_{1-6})alkyl; provided that, when Z is unsubstituted phenyl, then R^1, R^2 and R^3 do not each simultaneously represent methyl." Such compounds are not taught or suggested by the '246 publication.

The '246 publication teaches 2-aryl-4,5-dihydroxy-6-carboxypyrimidines of formula I that exist in equilibrium with tautomeric forms such as those of formula IA. *See* '246 publication, page 1, line 25 – page 2, line 12.



I IA

The Office Action acknowledges that the compounds set forth in claim 1 differ from those disclosed in the '246 publication in that R^1 is hydrogen in the publication. However, the Office Action takes the position that it would have been obvious to one of ordinary skill in the art to replace the hydrogen with the optionally substituted alkyl or arylalkyl groups of R^1 as claimed. Applicants respectfully disagree.

The Patent Office bears the initial burden of presenting a *prima facie* case of unpatentability. *In re Oetiker* 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). However, this burden is not met, at least because the Office Action asserts that "the structural similarity of compounds differing by a methyl in place of a hydrogen ... is well established," but fails to indicate where this similarity is "well established." As discussed below, the R^1 alkyl substitution of nitrogen in the pending claims provides an important distinction from the compounds of the '246 publication, any structural similarity notwithstanding.

The cited '246 publication teaches that compounds of its formula I are tautomeric; that is, the compounds of the '246 publication undergo tautomeric rearrangements in which hydrogen from a ring enol moves to the adjacent nitrogen and back. These tautomeric forms exist because the ring nitrogens are unsubstituted. When the ring nitrogen has an alkyl substitutent, as in R^1 of the claimed compounds, the

compounds cease to exist as tautomers. Thus, the claimed compounds are distinct from and patentable over the compounds disclosed in the '246 publication.

The '246 publication does not provide any motive to inhibit the tautomerization of its compounds and in particular does not teach or suggest alkyl substitution of its ring nitrogens. For at least this reason, the '246 publication does not teach or suggest the compounds of claim 1 and its dependent claims.

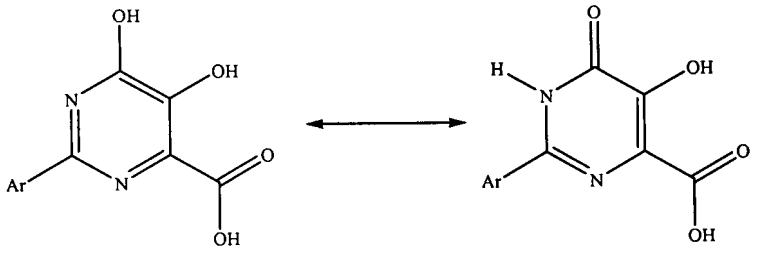
Accordingly, claim 1 and its dependent claims are not obvious over the '246 publication. Reconsideration and withdrawal of the rejection are respectfully requested.

III. Double Patenting Rejection

The Office Action rejects claims 1, 3-9, 13 and 14 under the judicially created doctrine of obviousness-type double patenting over claims 1-7 and 9-15 of U.S. Patent No. 7,091,209 to Gardelli et al. Applicants respectfully traverse this rejection with respect to claims 1, 3-9 and 14, claim 13 having been canceled herein.

Independent claim 1 is as set forth above.

The '209 patent claims priority to and contains the same disclosures as the PCT International Application that published as the '246 publication. The '209 patent teaches and claims, in claims 1-7 and 9-15, 2-aryl-4,5-dihydroxy-6-carboxypyrimidines of formula I that exist in equilibrium with tautomeric forms such as those of formula IA. *See* '209 patent, col. 1, line 35 – col. 2, line 4.



I IA

The compounds claimed in the '209 patent are tautomeric, like those of the '246 publication, and the '209 patent, like '246 publication, does not provide any motive to inhibit the tautomerization of its compounds and in particular does not teach or suggest alkyl substitution of its ring nitrogens. Thus, the compounds of the pending claims are distinct from and patentable over the compounds disclosed and claimed in the '209

patent. For at least this reason, the '209 patent does not teach or suggest the compounds of claim 1 and its dependent claims.

Accordingly, claim 1 and its dependent claims are not obvious over claims 1-7 and 9-15 of the '209 patent. Thus, reconsideration and withdrawal of the obviouness-type double-patenting rejection are respectfully requested.

IV. Conclusion

In view of these amendments and arguments, Applicants respectfully submit that this application is in condition for allowance. The Examiner is invited to contact the undersigned at the telephone number set forth below, should he believe that anything further is necessary to place this application in even better form for allowance.

Please charge Deposit Account No. 13-2755 for any fees due in connection with this Amendment. If any time extensions are needed for the timely filing of this Amendment, Applicants petition for such extensions and authorize the charging of Deposit Account No. 13-2755 for the necessary fees.

Respectfully submitted,

By _____

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